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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,822	REMACLE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *1-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/15/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in response received 23 September 2003 is acknowledged.

2. Claims 1-44 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in response received 23 September 2003.

Information Required

3. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

4. In response to this requirement, please identify that material/text/disclosure which was added to the instant application over that of the parent application US Patent Application Serial No. 09/582,817.

5. In response to this requirement, please identify that material/text/disclosure which was added to the instant application over that of the priority document, Provisional Application 60/071,726.

6. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to develop the disclosed subject matter that describes the applicant's invention, particularly as to developing CDs that comprise

microchannels and chambers on one side and further comprising registered data. For each publication, please provide a concise explanation of the reliance placed on that publication in the development of the disclosed subject matter.

7. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to draft the claimed subject matter. For each publication, please provide a concise explanation of the reliance placed on that publication in distinguishing the claimed subject matter from the prior art.

8. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

9. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Specification

10. The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

11. Appropriate correction is required.

12. The use of the trademarks TRITON X-100, and TWEEN have been noted in this application. They should be capitalized wherever they appear and be accompanied by their generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 45-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

16. For convenience, Claim 45, the only independent claim, is reproduced below.

> **45.** A disc comprising registered data, and bound upon its surface, one or more non-cleavable capture molecule(s) which allow for binding with one or more target molecule(s) to be detected, identified and/or quantified.

17. For purposes of examination, said "disc" has been interpreted as being of virtually any diameter and thickness. Said disc has also been interpreted as encompassing an infinite number of bound nucleic acids; that the "registered data" can be surface perturbations of grooves that are in turn read by a laser; and that bound capture probes/nucleic acids and registered data can be on the same side as well as within an infinite number of channels and chambers located within the disc.

18. A review of the disclosure fails to find an adequate written description of the genus of embodiments fairly encompassed by the claims. Page 9 of the specification states in part:

> The disc is in general of 1.2 mm thick and 4.72 inches in diameter, but smaller supports also exist and could be adapted for specific applications (such as binding between a capture and a target molecules into a Petri dish), and the thickness can. be adapted according to the technical requirements of the capture molecule and the detection method of the invention used.

19. Page 11 of the disclosure states in part:

> The disc according to the invention having fixed upon its surface the capture molecule may comprise either a protective layer possibly made of organic compounds which allow or improve protection and stabilization of "capture" molecules such as a layer made of proteinic and/or saccharidic compounds like albumin, disaccharides (such as trehalose, etc.) or a layer to improve the binding of capture molecules upon the solid support surface.

Pages 56-57 disclose that in conducting the assay, silver staining was performed. It is noted with particularity that the device used in the method did not comprise registered data, but simply comprised immobilized nucleic acid probes.

Page 63 (Example 9) teaches that chambers were fashioned not in the disc per se, but as a result of the disc having a plastic sheet applied.

Example 9: Multiple sample analysis in the different molded chambers present on the same disc platform.

The experimental protocol was identical as described in example 7 with the disc platform covered by a plastic sheet including 20 cavities for making chambers once applied on the CD. 9 duplex PCR products were made on 9

It is significant to noted that the chambers were "on" the disc, not in the disc, and that the chambers were fashioned by the plastic sheet, no the otherwise smooth surface of the disc. Accordingly, the specification does not support the position that applicant had possession of a disc of virtually any dimension and which had both registered data on one or both sides and immobilized nucleic acids. In view of the use of silver staining protocols, the specification does not provide an adequate written description of a disc, once used, could have any registered data read from its surface. The specification also does not provide an adequate written description of any disc where the disc comprises as a permanent and integral part, channels and chambers. Accordingly, the specification does not reasonably suggest that applicant possessed the full genus of embodiments encompassed by the claims.

The specification has been found to contain statements that modifications and alternative embodiments are fairly encompassed. Such assertions are considered an attempt to satisfy the written description requirements through obviousness. Obviousness, however, cannot be relied

upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Accordingly, and in the absence of convincing evidence to the contrary, claims 45-86 are rejected under 35 USC 112, first paragraph.

20. Claims 45-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

21. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or

> guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

22. As set forth above, the claims fairly encompass innumerable species that the specification does not reasonably suggest that applicant was in possession of at the time of filing. It stands to reason, therefore, that one cannot enable that which they do not yet possess.

23. A review of the disclosure finds 16 examples. Of these examples, only the following examples appear relevant to the claimed device and the elected species:

- Example 1 (pages 47-49),
- Example 2 (page 49);
- Example 6 (pages 54-55);
- Example 7 (pages 55-59); Example 8 (pages 59-63);
- Example 9 (page 63);
- Example 10 (pages 63-64),
- Example 11 (page 64), and
- Example 12 (pages 64-66).

The disc utilized in the above-identified examples are limited to that identified as a "CD." It is further noted that silver staining was used such that a detectable hybridization signal could be obtained; yet none of the examples disclosed the reading of registered data subsequent to signal detection (silver staining). The disclosure does not set forth a reproducible procedure whereby multiple addresses on an array are tested/evaluated serially, where different probes are used in a

series of, and the specification does not teach in sufficient detail how a disc is constructed and used whereby it comprises as an inherent property, channels and chambers. Rather, the specification teaches of temporarily applying a plastic sheet. Even with the aspect of using a plastic sheet in a transient manner, the specification does not set forth a reproducible procedure whereby such a plastic sheet is fashioned and then aligned with the appropriate groves on a CD. The specification also does not disclose what glue is used to affix the plastic sheet to aid CD such that once removed, the plastic and associated glue/fixative will be removed and thereby permit reading. Accordingly, applicant has not provided the requisite starting materials and reaction conditions.

24. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are not enabled by the disclosure.

25. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claims 45-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

27. Said claims are indefinite with respect to just what constitutes "registered data."

Conclusion

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
09 February 2004

Notice to Comply	Application No.	Applicant(s)	
	10/035,822	REMACLE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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